

Emory IRB

Study Team

WIRB

Study team submits completed **Form A** and adds to eIRB submission

- 1) Study Team completes eIRB smartform according to guidelines.** Ensure completion of the following:
- Submit study to correct department for review
 - Ancillary Reviews and ICF options
 - Radiation Safety
 - Biosafety
 - CRTC
 - Office of Quality*
 - ICOI option from OSP**
 - Cost option from OCR**
- 2) Study team submits to Connexus**

Once all pending items are completed, AA sends **Institutional Sign-off**

Director or designee reviews ICF deviations and provides Ok (or refusal).

AA sends ICFs to OCR; all docs to OTT. If there are ICF deviations (from approved Cost and ICOI language), and we cannot accept them, the AA will send study back to WIRB asking for AM submission to correct. If there are no additional ICF deviations (or were accepted), AA will **remove the institutional hold; otherwise request amendment or Director sign off**. AA saves a copy of the approved documents in the study history as a private comment.

WIRB receives submission; does not review until receiving **Institutional Sign-Off** from Emory

WIRB screens documents. If any deviations from Emory language, requests Emory additional review.

After accepting deviations, WIRB Full Board reviews study. After Board approval, WIRB sends approved documents to Emory IRB.

WIRB releases regulatory documents to study team and IRB

Study Team receives approval documents from WIRB

For continuing review, amendment or reportable event submission, the study team submits directly to WIRB without Emory intervention.

*OoQ checklist not required for sign-off, but required for hold removal

** IRB Analyst can issue institutional sign off without ICOI or Cost option if study team submits and AM to WIRB after study approval if any change in these options.